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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,374	03/26/2001	Daniel Delorme	106101.139	9679
7590		12/11/2003	EXAMINER	
Wayne A Keown		BALASUBRAMANIAN, VENKATARAMAN		
500 West Cummings Park		ART UNIT		
Suite 2900		PAPER NUMBER		
Woburn, MA 01801		1624		

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/817,374	Applicant(s) DELORME ET AL.	
	Examiner Venkataraman Balasubramanian	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-21,23-33,35-39,42-44 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) 50 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-21,23-33,35-39,42-44 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, which included amendment to claims 1, 4, 18, 21, 33, 42, 43, 47, 48, and cancellation of claims 5, 22, 34, 40-41, 45-46, 52-56, filed on 7/28/2003, is made of record.

Claims 1-4, 6-21, 23-33, 35-39, 42-44, and 47-49 are under examination. Note these claims still have non-elected subject matter and would be examined to the extent they embrace the elected subject matter. Pending claims 50-51, which belong to non-elected group(s), were withdrawn from consideration as noted in the previous office action.

Applicant is reminded that upon the amendment and or cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

There seems to be some typographical errors in the pending claims and it is not clear whether these are due to image scanning or the errors were in the amended claims. See for example claim 19, the names of the heterocyclic groups and the word "consisting" in Z definition of claim 30.

In view of applicants' response all 112 rejections made in the previous office action have been obviated. In addition, 102 rejection over Cohen is withdrawn as it does not as pointed out by the applicants meet the requirement of W group.

However, the following new rejections are applied.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-21, 23-33, 35-39, 42-44, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of the term “comprises” in claim 1 and other dependent claims, render these claims indefinite the transitional phrase ‘comprises’ is open-ended and can include more than what is being positively recited therein. See MPEP 2111.03 which states: The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ

- 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").
2. Claims 1, 18, 30, 42-43, and 47-48 recite the limitation "the liner chain" in these claims. There is insufficient antecedent basis for this limitation in the claim.
 3. The definition of Z in claim 1 and other claims as to "anilinyI" is confusing. As recited it implies the point of attachment is through nitrogen but reading claim 15, it appears that the attachment is through ring carbon. An appropriate correction is required.
 4. Recitation of M as "or a pharmaceutically acceptable cation" in NHOM of W definition in claim 1 and other claims wherever it appears, is vague and unclear as a cation can be more than monovalent and such case the valence requirement of M is not met with. For example, a pharmaceutically acceptable cation can be calcium or magnesium as noted in claim 15 but in such cases what is appended to second valence of these cations remains unknown.
 5. Recitation of "one to about three carbon atoms" in claim 7 renders claim 7 vague and unclear. Deletion of "about" is suggested.
 6. Claim 10 does not end with a period.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-33, 35-37, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurihara et al., WO 99/04780 (equivalent US 6,423,729, also provided).

Kurihara et al. teaches several sulfonamide compounds, which include compounds claimed in the instant claims, for treating glomerulopathy. See formula I and note when Y is NHOH, the compounds taught by Kurihara et al. include those claimed in the instant invention. See entire document, especially formula VII, VIII, XIII, XIV, XVII, XIX and XXI-XXIII and Table I on pages 14-24 for various thiophene sulfonamides.

Claims 30-33, 35-37, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kukkola et al., WO 99/42443 .

Kukkola et al. teaches several sulfonamide compounds, which include compounds claimed in the instant claims, for treating metalloproteinases mediated diseases. See formula I and note the definition of various variable groups. Note when W is NHOH, the compounds taught by Kukkola et al. include those claimed in the instant invention. See entire document, especially examples 18-30 on pages 41- through 47 for various thiophene sulfonamides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-33, 35-37, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al., WO 99/04780.

Teachings of Kurihara et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Kurihara et al. teaches several sulfonamide compounds, which include compounds claimed in the instant claims, for treating glomerulopathy.

Kurihara et al. differs from the reference in not exemplifying all compounds with thiophene core generically embraced in the formula I, but Kurihara teaches representative examples of making various thiophene sulfonamide compounds.

However, Kurihara et al. teaches equivalency of the exemplified thiophene compounds with those compounds generically claimed in the definition of various variable groups on pages 3-5. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted the thiophene ring and the side chain as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 30-33, 35-37, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kukkola et al., WO 99/42443.

Teachings of Kukkola et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Kukkola et al. teaches several sulfonamide compounds, which include compounds claimed in the instant claims, for treating metalloproteinases mediated diseases.

Kukkola et al. differs from the reference in not exemplifying all compounds with thiophene core and those compounds with furan core generically embraced in the formula I, but Kukkola teaches representative examples of making various thiophene sulfonamide compounds.

However, Kukkola et al. teaches equivalency of the exemplified thiophene compounds with those compounds generically claimed in the definition of various

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variable groups on pages 1-2. Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make compounds variously substituted the thiophene ring and the side chain including the furan core compounds as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Allowable Subject Matter

Claims 1-4, 6-21, 23-29, 42-43, and 47-49 would be allowable, barring finding of any prior art in a subsequent search, to the extent they embrace the elected subject matter if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. Said claims would be allowed since specific species, composition and method of use embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

12/09/2003